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ANDREW WASSERMAN

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ANDREW WASSERMAN,

Plaintiff,

v.

JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and DOES 1-5,

Defendants.

Case No. 14-CV-02739-VC

JOINT CASE MANAGEMENT STATEMENT AND [PROPOSED] CASE MANAGEMENT ORDER

Judge: Hon. Vince Chhabria
Date: September 16, 2014
Time: 10:00 a.m.
Courtroom: 4

Pursuant to the Court's July 21, 2014 Order Setting Initial Case Management Conference, and the Standing Order for All Judges of the Northern District of California, Plaintiff ANDREW WASSERMAN and Defendants JANSSEN PHARMACEUTICALS, INC. ("Janssen"), JOHNSON & JOHNSON ("J&J"), and JANSSEN RESEARCH AND DEVELOPMENT, LLC ("JRD") (collectively "Defendants" and, together with Plaintiff, the "Parties") hereby jointly submit this Joint Case Management Statement and Proposed Case Management Order. The Parties held Rule 26(f) conferences on August 14, 2014 and August 25, 2014, regarding the matters contained in the Standing Order for All Judges of the Northern District of California, and the Federal Rule of Civil Procedure 26, as discussed in this statement. Where the Parties are unable to agree, their separate positions are stated.

1. Jurisdiction and Service: The basis for the Court's subject matter jurisdiction over Plaintiff's claims is 28 U.S.C. § 1332. All known parties have been served. At the present time, Defendants do not anticipate challenging venue. Defendants reserve the right to do so in the future as discovery commences. The Parties have discussed the potential dismissals of J&J and JRD, and will continue to meet and confer regarding same.

2. Facts: Plaintiff alleges that he was prescribed and took Janssen's product, Risperdal® (and/or generic Risperidone), beginning at age 20 in 2008 and at various times until 2013. Plaintiff alleges that Janssen failed to warn Plaintiff's prescribing physician(s) of gynecomastia, that Plaintiff's use of Risperdal® caused him to develop gynecomastia, that Plaintiff's gynecomastia required surgical intervention in April 2011, and that Janssen's failure to warn was the direct and proximate cause of Plaintiff's injuries.

Defendants have insufficient information to admit or deny that Plaintiff was prescribed and took Risperdal®. Plaintiff will be producing medical and prescription records. However, Defendants deny that Janssen failed to warn Plaintiff's prescribing physician(s) of the side-effects of Risperdal®. Information concerning elevated prolactin and gynecomastia has appeared in the Risperdal® label since its initial approval by the FDA in 1993. Defendants contend that Janssen has at all times manufactured, marketed, and/or distributed Risperdal® in accordance with the FDA approved Risperdal® package insert. Defendants refer to their Answer, filed on July 29,

2014, for admissions and denials as to the remaining claims contained in Plaintiff's First Amended Complaint (hereinafter, "Complaint").

The principal factual issues in dispute include, among other things:

- Whether Risperdal® can cause gynecomastia, i.e., general medical causation;
- Whether Plaintiff has or has had gynecomastia;
- Whether Risperdal® caused gynecomastia in Plaintiff, i.e. specific medical causation;
- Whether Plaintiff's prescribing physician(s) was informed whether gynecomastia is an adverse event reported in patients using Risperdal®;
- Whether any alleged failure to warn caused or contributed to Plaintiff's injures.

3. Legal Issues: Plaintiff asserts claims against Defendants under theories of strict products liability, negligence, negligence *per se*, false advertising, fraudulent concealment, fraudulent misrepresentation, failure to warn, breach of express and implied warranties, unfair business practices, and intentional infliction of emotional distress. Defendants deny that they are liable to Plaintiff in any way.

The disputed points of law include:

- Whether Plaintiff's claims are preempted by FDA regulations and/or actions;
- Whether Plaintiff's claims are barred by the learned intermediary doctrine;
- Whether Plaintiff's claims are barred by applicable statutes of limitation;
- Whether Plaintiff's claims fail for lack of general and/or specific causation;
- Whether choice of law principles require the application of California law or the laws of other states to Plaintiff's claims;
- Whether Plaintiff may pursue punitive damages; and
- Whether the warnings provided by Janssen for its product, Risperdal®, were adequate as a matter of law.

4. Motions: Defendants anticipate filing motions for summary judgment, *Daubert* motions, and motions in limine as to, among other issues, the adequacy of Janssen's warnings for its product, Risperdal®.

5. Amendment of Pleadings: The Parties do not anticipate filing amendments to their pleadings at this time. The deadline for amending the pleadings as a matter of course was August 19, 2014.

6. Evidence Preservation: The Parties have reviewed the Guidelines Relating to the Discovery of Electronically Stored Information ("ESI Guidelines"), and have met and conferred pursuant to Fed. R. Civ. P. 26(f) regarding reasonable and proportionate steps taken to preserve evidence relevant to the issues reasonably evident in this action. The Parties are not aware of any such issues at this time. The Parties will meet and confer regarding an ESI agreement, consistent with the ESI Guidelines.

Litigation holds by Janssen relating to its product, Risperdal®, have been in place for several years. Documents containing potentially relevant information, including electronically stored information ("ESI"), have been collected and preserved in connection with prior actions.

7. Disclosures: The Parties have made full and timely initial disclosures pursuant to Rule 26. Defendants' disclosures included, to the extent known, a list of individuals likely to have information concerning Plaintiff's use of Risperdal®, and Plaintiff's diagnosis and treatment of gynecomastia; and a list of relevant categories of documents on which Defendants are likely to rely, including product labels. Plaintiff's disclosures included, to the extent known, the identity of all medical treaters who provided medical care to Plaintiff, all medical facilities where each treatment took place, and all individuals with knowledge of Plaintiff's alleged use of Risperdal and Plaintiff's injuries.

8. Discovery: No discovery has been taken to date. The Parties anticipate that discovery will be conducted regarding the following subjects:

- The factual bases for Plaintiff's allegations and Defendants' defenses;
- The factual circumstances surrounding Plaintiff's alleged use of Risperdal®;
- Any and all records from medical doctors, psychologists, psychiatrists, or other healthcare professionals who have treated Plaintiff for conditions relating to the claims asserted in Plaintiff's Complaint;
- Plaintiff's medical history prior to and after the events alleged in the Complaint;

- Alleged representations to Plaintiff by Defendants;
- The cause(s) of Plaintiff's alleged medical conditions and/or purported injuries;
- The nature and extent of Plaintiff's alleged damages; and
- The factual bases for Plaintiff's claim for punitive damages.

Because this case is still in the early stages of litigation, other subjects may likely become relevant as discovery continues and as the Parties prepare for trial.

The Parties will meet and confer regarding a protocol for collection of authorizations to release medical records.

The Parties anticipate serving requests for production of documents, interrogatories, requests for admissions, and deposition notices as appropriate. Defendants anticipate serving a demand for physical or mental examinations.

Discovery of Electronically Stored Information

Janssen may in the future produce documents (electronic or otherwise) in this litigation that have been previously formatted and produced for other litigation involving Risperdal®. Janssen will meet and confer with Plaintiff to ensure that the production formats used by Janssen in prior or ongoing litigation elsewhere conform to the ESI Guidelines.

Claims of Privilege and Protection of Trial-Preparation Materials

The Parties have met and conferred regarding a Protective Order to govern the use of confidential materials, address claims of privilege and/or work product doctrine, and protect trial preparation materials. The parties have agreed upon a Proposed Protective Order a copy of which is filed herewith in the form of a Stipulation and Order. The Proposed Protective Order is virtually identical to one entered by Judge Highberger in the coordinated proceedings in Los Angeles Superior Court, known as Risperdal® and Invega® Product Liability Cases, JCCP No. 4775. A separate Stipulation and Proposed Order will be filed with the Court.

Changes to Limitations Imposed by Federal and Local Civil Rules

At this time, the Parties do not find it necessary to modify the limitations set forth in the Federal Rules of Civil Procedure as they pertain to discovery.

9. Class Actions: This case is not a putative class action.

10. Related Cases: In March 2010, a coordinated Risperdal mass tort proceeding, known as *In re Risperdal Litigation*, which involves more than 600 cases, was created in the Court of Common Pleas of Philadelphia. In March 2014, a number of cases filed throughout California were coordinated in Los Angeles County Superior Court, known as *Risperdal® and Invega® Product Liability Cases*, JCCP No. 4775. In addition, Defendants are aware of a small number of federal cases involving Risperdal® and failure to warn claims. The parties do not assert that the foregoing cases constitute a "related case" for purposes of L.R. 3-12.

11. Relief: Plaintiff claims compensatory and punitive damages for his alleged injuries. Defendants deny Plaintiff is entitled to any relief sought, and assert that there is no basis for Plaintiff's claim for punitive damages under applicable law.

12. Settlement and ADR: At this time, the Parties are unable to report on the prospects for settlement and have not yet engaged in any form of ADR. The parties have agreed to proceed with Early Neutral Evaluation ("ENE") and have filed an ADR Stipulation with the Court proposing an ENE date 120 days out. The Parties do not anticipate a need for Court mediated settlement and do not request a settlement conference at this time.

13. Consent to Magistrate Judge For All Purposes: The Parties do not consent to have a magistrate judge conduct all further proceedings, including trial and entry of judgment.

14. Other References: The Parties are not aware of any special considerations that make this action suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

15. Narrowing of Issues: Except for anticipated motion(s) for summary judgment, *Daubert* motions, and motions in limine as to adequacy of Janssen's warnings for its product, Risperdal®, the Parties are not aware of any issues at this time that can be narrowed by agreement or by motion. The Parties have no suggestions to expedite the presentation of evidence at trial at this time. The Parties have no requests to bifurcate issues, claims, or defenses at this time.

16. Expedited Trial Procedure: Expedited Trial Procedure of General Order No. 64 is not applicable to this action.

17. Scheduling: The Parties request the court adopt the following proposed case management schedule at this time:

	Parties' Joint Proposed Schedule
Fact discovery cut-off	6/2015
Plaintiff's expert designations and reports due under Fed. R. Civ. P. 26(a)(2)	7/2015
Defendants' expert designations and reports due under Fed. R. Civ. P. 26(a)(2)	9/2015
Last date to notice Dispositive Motions	10/2015
Pre-trial conference	12/2015
Trial	2/2016

18. Trial: Each party requests a jury trial. The Parties anticipate the length of the trial will be approximately 12 to 15 court days.

19. Disclosure of Non-party Interested Entities or Persons: Defendants have jointly filed their "Certification of Interested Entities or Persons" on July 29, 2014, as required by Civil Local Rule 3-16. Specifically, Janssen and J&J each certify that, as of this date, other than the named parties, there is no such interest to report. JRD identified Centocor Research & Development, Inc. as an interested entity pursuant to Civil Local Rule 3-16. Centocor Research & Development, Inc.'s parent company is Janssen Biotech, Inc. Janssen Biotech, Inc. is a wholly owned subsidiary of J&J.

20. Other Matters: None at this time.

APPROVED:

Dated: September 8, 2014

DRINKER BIDDLE & REATH LLP

By: */s/ John J. Powers*
John J. Powers
Sanjeet S. Ganjam

Attorneys for Defendants
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, and JANSSEN RESEARCH AND DEVELOPMENT, LLC

Dated: September 8, 2014

LAW OFFICE OF AARON MYERS

By: */s/ Aaron Myers*
Aaron Myers

Attorney for Plaintiff
ANDREW WASSERMAN

IT IS SO ORDERED:

Dated: September _____, 2014

The Honorable Vince Chhabria
United States District Court Judge

Attestation Pursuant to Civil Local Rule 5-1(i)

Pursuant to Civil Local Rule 5-1(i), I, John J. Powers hereby attest that I have obtained concurrence in the filing of this document from the other signatory to this document.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on September 8, 2014 in San Francisco, California.

/s/ John J. Powers
John J. Powers